

Citation:

Niinikoski H, Lagström H, Jokinen E, Siltala M, Rönnemaa T, Viikari J, Raitakari OT, Jula A, Marniemi J, Näntö-Salonen K, Simell O. Impact of repeated dietary counseling between infancy and 14 years of age on dietary intakes and serum lipids and lipoproteins: The STRIP study. *Circulation*. 2007 Aug 28; 116 (9): 1,032-1,040.

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Study Design:

Prospective Cohort Study

Class:

B - [Click here](#) for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To investigate the effects of low-saturated fat, low-cholesterol dietary counseling on dietary intakes, growth and serum lipid, lipoprotein and apolipoprotein values until 14 years of age.

Inclusion Criteria:

Infants at five-month well-baby clinic visit in Turku, Finland between 1990 and 1992.

Exclusion Criteria:

Not reported.

Description of Study Protocol:**Recruitment**

Families were recruited at well-baby clinics in Turku, Finland at the infants' five-month visit between 1990 and 1992.

Design

Prospective cohort study.

Dietary Intake/Dietary Assessment Methodology

Annual four-day food records (three-day records before two years of age) with nutritionist review of records and nutrient calculation with software.

Intervention

- *Nutrition intervention:*

- Families visited the counseling team at one to three month intervals until the child reached two years of age and twice a year thereafter
- The intervention was individualized for each child and aimed at achieving a fat intake of 30% to 35% of daily energy, with a ratio of saturated to monounsaturated plus polyunsaturated fatty acid of 1:2 and cholesterol intake less than 200mg per day
- Breastfeeding or formula was recommended during the first year of life, then 0.5 to 0.6L of skim milk was advised. The addition of two to three teaspoons of fat to the child's diet was recommended from 12 to 24 months of age
- Families were encouraged to gradually change the child's diet toward better fat consumption. Intake of vegetables, berries and whole grain products was encouraged.

- *Control intervention:*

- Families were seen by the same team twice a year until the child reached seven years of age, and then once a year thereafter
- They received basic health education routinely given at well-baby clinics through school health care
- Dietary issues were discussed superficially.

Statistical Analysis

- Repeated measures ANOVA was conducted for lipid values, food intakes and growth measures across the age points seven months to 14 years
- Multivariate repeated-measured ANCOVA models were used to adjust the intervention effect on serum lipid values with energy intake, saturated fatty acid intake (as a percent of energy intake), height (SD) and body mass index (BMI)
- Triglycerides, weight and BMI were analyzed after logarithmic transformation
- Sex and intervention group with interaction terms were included in all analyses.

Data Collection Summary:

Timing of Measurements

- Food consumption data were obtained annually
- Blood samples were drawn for serum lipid and apolipoprotein concentrations at seven months, 13 months, two years of age and annually thereafter (non-fasting samples were collected before five years of age and fasting samples thereafter).

Dependent Variables

- Serum cholesterol concentration (total, LDL, HDL, apolipoprotein): Measured with a fully enzymatic cholesterol oxidase-p-aminophenazone method
- Serum triglyceride level: Analyzed with the colorimetric GPO-PAP method
- BMI: Height and weight measured directly.

Independent Variables

Intervention or control group.

Control Variables

- Energy intake
- Saturated fatty acid intake (as a percentage of energy intake)

- Height (SD)
- BMI.

Description of Actual Data Sample:

- *Initial N*: 1,062
- *Attrition (final N)*: 532 at 14 years
 - 256 girls
 - 276 boys
- *Age*: Followed from age seven months through 14 years
- *Location*: Turku, Finland.

Summary of Results:

Key Findings

- There were no differences in heights ($P=0.44$), weights ($P=0.27$) and BMIs ($P=0.28$) between the intervention and control groups
- The dietary intervention significantly influenced serum lipid and lipoprotein values throughout childhood, and the difference between intervention and control children persisted in serum cholesterol through 14 years of age in boys ($P<0.001$), but the difference in girls was not significant ($P=0.043$)
- Differences between intervention and control groups were not seen in HDL cholesterol levels
- For serum triglyceride, the intervention had an effect only in boys
- Adjustment for energy intake, saturated fatty acid intake (percentage of energy), height (SD) and BMI did not change results; the intervention effect remained significant in serum LDL concentration and HDL ratio in both genders and on serum cholesterol and triglyceride concentration in boys.

Other Findings

- The intervention children had lower fat and saturated fat intakes (both $P<0.001$) than control children, whereas protein and carbohydrate intakes were higher in the intervention than control children (both $P<0.001$)
- The energy intake of the intervention children, especially the boys, was slightly lower than that of the control children throughout the study.

Author Conclusion:

A low-saturated fat-, low-cholesterol-oriented nutrition intervention had a favorable effect on saturated fat intake and serum total and LDL cholesterol concentrations throughout the first 14 years of life.

Reviewer Comments:

Study Strengths

- *Long follow-up period*
- *Statistical analyses looked at several potential confounders and interactions between*

variables

- Objective measurements for height and weight.

Study Limitations

- Self-reported or parent-reported dietary intake; participants in intervention group may have been more likely to give desirable answers
- Counseling was individualized, so exposure varied for each participant
- 50% follow-up at 14 years of age.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

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|----|---|-----|
| 1. | Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies) | Yes |
| 2. | Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about? | Yes |
| 3. | Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice? | Yes |
| 4. | Is the intervention or procedure feasible? (NA for some epidemiological studies) | Yes |

Validity Questions

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|------|---|-----|
| 1. | Was the research question clearly stated? | Yes |
| 1.1. | Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified? | Yes |
| 1.2. | Was (were) the outcome(s) [dependent variable(s)] clearly indicated? | Yes |
| 1.3. | Were the target population and setting specified? | Yes |
| 2. | Was the selection of study subjects/patients free from bias? | Yes |
| 2.1. | Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study? | Yes |
| 2.2. | Were criteria applied equally to all study groups? | Yes |
| 2.3. | Were health, demographics, and other characteristics of subjects described? | Yes |
| 2.4. | Were the subjects/patients a representative sample of the relevant population? | ??? |

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| 3. | Were study groups comparable? | Yes |
| 3.1. | Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT) | Yes |
| 3.2. | Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline? | ??? |
| 3.3. | Were concurrent controls used? (Concurrent preferred over historical controls.) | Yes |
| 3.4. | If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis? | N/A |
| 3.5. | If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.) | N/A |
| 3.6. | If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")? | N/A |
| 4. | Was method of handling withdrawals described? | Yes |
| 4.1. | Were follow-up methods described and the same for all groups? | Yes |
| 4.2. | Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.) | Yes |
| 4.3. | Were all enrolled subjects/patients (in the original sample) accounted for? | Yes |
| 4.4. | Were reasons for withdrawals similar across groups? | ??? |
| 4.5. | If diagnostic test, was decision to perform reference test not dependent on results of test under study? | N/A |
| 5. | Was blinding used to prevent introduction of bias? | Yes |
| 5.1. | In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate? | No |
| 5.2. | Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.) | Yes |
| 5.3. | In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded? | N/A |
| 5.4. | In case control study, was case definition explicit and case ascertainment not influenced by exposure status? | N/A |

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| 5.5. | In diagnostic study, were test results blinded to patient history and other test results? | N/A |
| 6. | Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described? | Yes |
| 6.1. | In RCT or other intervention trial, were protocols described for all regimens studied? | Yes |
| 6.2. | In observational study, were interventions, study settings, and clinicians/provider described? | N/A |
| 6.3. | Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect? | Yes |
| 6.4. | Was the amount of exposure and, if relevant, subject/patient compliance measured? | Yes |
| 6.5. | Were co-interventions (e.g., ancillary treatments, other therapies) described? | N/A |
| 6.6. | Were extra or unplanned treatments described? | N/A |
| 6.7. | Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups? | N/A |
| 6.8. | In diagnostic study, were details of test administration and replication sufficient? | N/A |
| 7. | Were outcomes clearly defined and the measurements valid and reliable? | Yes |
| 7.1. | Were primary and secondary endpoints described and relevant to the question? | Yes |
| 7.2. | Were nutrition measures appropriate to question and outcomes of concern? | Yes |
| 7.3. | Was the period of follow-up long enough for important outcome(s) to occur? | Yes |
| 7.4. | Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures? | Yes |
| 7.5. | Was the measurement of effect at an appropriate level of precision? | Yes |
| 7.6. | Were other factors accounted for (measured) that could affect outcomes? | Yes |
| 7.7. | Were the measurements conducted consistently across groups? | Yes |
| 8. | Was the statistical analysis appropriate for the study design and type of outcome indicators? | Yes |
| 8.1. | Were statistical analyses adequately described and the results reported appropriately? | Yes |
| 8.2. | Were correct statistical tests used and assumptions of test not violated? | Yes |

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| 8.3. | Were statistics reported with levels of significance and/or confidence intervals? | Yes |
| 8.4. | Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)? | No |
| 8.5. | Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)? | Yes |
| 8.6. | Was clinical significance as well as statistical significance reported? | No |
| 8.7. | If negative findings, was a power calculation reported to address type 2 error? | N/A |
| 9. | Are conclusions supported by results with biases and limitations taken into consideration? | Yes |
| 9.1. | Is there a discussion of findings? | Yes |
| 9.2. | Are biases and study limitations identified and discussed? | No |
| 10. | Is bias due to study's funding or sponsorship unlikely? | Yes |
| 10.1. | Were sources of funding and investigators' affiliations described? | Yes |
| 10.2. | Was the study free from apparent conflict of interest? | Yes |